IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MONTANA

BILLINGS DIVISION

RANDEE PARSONS AND PEGGY PARSONS, Plaintiffs, vs. SISTERS OF CHARITY OF LEAVENWORTH HEALTH SYSTEM, INC., A KANSAS CORPORATION; BLUE CROSS AND BLUE SHIELD OF KANSAS CITY, A MISSOURI CORPORATION; AND BLUE CROSS BLUE SHIELD OF SOUTH CAROLINA FOUNDATION, A SOUTH CAROLINA CORPORATION, Defendants.	Cause No. CV 10-47-BLG-RFC ORDER GRANTING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

Presently before the Court are Defendants Sisters of Charity of Leavenworth ("Sisters of Charity") and Blue Cross Blue Shield of South Carolina and Blue

Cross Blue Shield of Kansas City's ("BCBS" collectively) motions for summary judgment. *Docs. 21 & 27.* At the Court's direction the Parties have supplemented their motions and responses with additional briefing regarding the application of Dr. Richard Burt's deposition to the issues of the case. *Doc. 67.* Having reviewed and considered the briefing in this case, this Court is prepared to rule. Given that many of the Defendants' summary judgment arguments overlap and all turn on the Defendants' denial of coverage for Plaintiff Randee Parsons's ("Parsons") participation in a clinical trial for ABMT/stem-cell transplant treatment, they will be treated, for purposes of this Order, as a single motion for summary judgment.

II. FACTUAL BACKGROUND

Twenty year old Randee Parsons suffers from refractory Crohn's disease, a severe autoimmune disease that inflames and attacks the victim's gastrointestinal tract. Crohn's disease is a chronic disease for which there is no known cure. Recently, treatment of Crohn's disease with autologous bone marrow transplants ("ABMT"), a type of stem cell transplant treatment, has been shown to be partially successful. Dr. Richard Burt, an immunologist at Northwestern Medical School, has been conducting a clinical trial on treating Crohn's disease with ABMT techniques. According to Plaintiffs, Dr. Burt's ABMT trial was approved, at least in part, by the Food and Drug Administration as well as the National Institutes of

Health.

In December 2009, Parsons sought and was granted admission into Dr. Burt's clinical trial. Plaintiffs allege that other patients in Dr. Burt's trial had received insurance coverage by their respective insurance companies. Parsons was covered by a Medical Plan issued to her mother through her employ a St. Vincent Healthcare Hospital, an affiliate of Defendant Sisters of Charity of Leavenworth Health System. Sisters of Charity's employee medical plan is self-insured and does not contract with any health insurance company against risk of loss, but it does contract with third-party administrators Defendants BCBS South Carolina and BCBS Kansas City for administrative services.

Parsons sought coverage for the clinical trial through the Sisters of Charity Medical Plan, but was denied. Based on the review of application and the terms of the Plan, on February 2, 2010, BCBS sent Plaintiffs a letter denying coverage of the ABMT treatment on the grounds that Dr. Burt's trial was "investigational and experimental" and not medically necessary.

Plaintiffs appealed BCBS' denial to Sisters of Charity's Benefit Administration Committee. As part of the appeals process, Sisters of Charity sought external independent review from gastroenterologists who had experience in Crohn's disease. These reviewers concluded that only a limited number of

Crohn's patients had ever been treated with ABMT techniques and that Dr. Burt's clinical trial was experimental and investigational and not medically necessary. In addition, this procedure was only available at "investigational centers of excellence under the overview of institutional research boards."[1] Ultimately, in a February 19, 2010 letter, the Benefits Administration Committee affirmed the denial of Plaintiffs' requested benefits.

Plaintiffs appealed a second time. This time, Dr. James Koren, the Associate Medical Director for Defendant BCBS of South Carolina contacted Dr. Burt in order to initiate a peer-to-peer discussion regarding Dr. Burt's research, as well as the ABMT procedure that he was seeking to perform on Parsons. Dr. Koren avers that during the conversation, Dr. Burt stated that other investigators in his field did not recognize his research and that there was a controversy within the clinical community regarding the effectiveness of ABMT/stem-cell transplant therapy for Crohn's disease.[2] Dr. Burt subsequently forwarded to Dr. Koren numerous abstracts and studies that Dr. Koren contends lead him to the conclusion that the ABMT procedure was still in the investigational and experimental stage.

In addition, on April 29 or 30th, Dr. Koren had a second conversation with

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[1] *AFFIDAVIT OF GENE LAMPE, Doc. # 24, ¶ 19.*

[2] *AFFIDAVIT OF JAMES KOREN, M.D. (Doc. # 29-1), ¶ 3.*

Dr. Burt. Dr. Koren states that this second conversation was at Sisters of Charity's request. It appears that no new information was gained from this conversation due to a deterioration in the cordial relationship of both participants.[3]

The relevant language in Sisters of Charity's Medical Plan makes clear that:

> REGARDLESS OF LANGUAGE CONTAINED ELSEWHERE IN THIS PLAN OF BENEFITS, THE FOLLOWING ARE NOT BENEFITS UNDER THE PLAN OF BENEFITS . . . BCBS WILL NOT PAY ANY AMOUNT FOR THE FOLLOWING . . . 1. Services and supplies that are not medically necessary as determined by the Plan Administrator . . . 5. Services, supplies or drugs that are Experimental and Investigational . . .[4]

The Plan defines "experimental and investigational" as,

> Surgical procedures or medical procedures, supplies, devices or drugs which, at the time provided or sought to be provided, are in the judgment of BCBS not recognized as conforming to generally accepted medical practice, or the procedure, drug or device:
> - Had not received final approval to market from appropriate government bodies; or,
> - Is one about which the peer-reviewed medical literature does not permit conclusions concerning its effect on health outcomes; or,
> - Is not demonstrated to be as established alternatives; or,
> - Has not been demonstrated to improve net health outcomes; or,
> - Is one in which the improvement claimed is not demonstrated to be obtainable outside the Experimental and Investigational setting.[5]

The Court notes that the criteria for "experimental and investigational" are stated

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[3] *AFFIDAVIT OF JAMES KOREN, M.D. (Doc. # 29-1), ¶ 7.*

[4] *SISTERS OF CHARITY MEDICAL PLAN, AFFIDAVIT OF GENE LAMPE, EXHIBIT A.*

[5] *Id.*

in the disjunctive.

The Plan defines "medically necessary/medical necessity" as,

> Benefits determined by BCBS (in the exercise of its discretion) to be:
> - Required to identify or treat an illness or injury; and,
> - Prescribed or ordered by a physician; and,
> - Consistent with the diagnosis and treatment of the Covered Member's condition; and,
> - In accordance with the standards of good medical practice; and,
> - Delivered in the most cost-effective setting; and,
> - Required for reasons other than convenience of the Covered Member or the Covered Member's Physician; and
> - not to be services, supplies or drugs that are Experimental or Investigational.[6]

In addition, Article IV, 4.1(b) of Sisters of Charity System Health Benefits Plan states, in relevant part, that:

> The Committee shall have complete discretion to interpret the provisions of the Plan, make findings of fact, correct errors, supply omissions, and determine the benefits payable under a Welfare Program. All decisions and interpretations of the Committee made in good faith pursuant to the Plan shall be final, conclusive and binding on all persons, subject only to the claims procedure, and may not be overturned unless found by a court to be arbitrary and capricious.[7]

Having exhausted their administrative remedies, Plaintiffs filed the instant action alleging the following claims: (1) Count I - breach of fiduciary duty in violation of Mont. Code Ann. § 33-32-201; (2) Count II - negligent utilization

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[6] *Id.*

[7] *Id.*

review pursuant to Mont. Code Ann. 33-32-201; (3) Count III - breach of insurance contract; (4) Count IV- causation; and (5) Count V - violation of Montana's Unfair Claim Settlement Practices Act pursuant to Mont. Code. Ann. § 33-18-201, *et. seq.*

III. STANDARD OF REVIEW

Summary judgment is appropriate only when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). The moving party has the initial burden of "identifying for the court those portions of the materials on file in the case that it believes demonstrate the absence of any genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). If the moving party meets its burden, then the opposing party may not defeat a motion for summary judgment in the absence of any significant probative evidence tending to support its legal theory. *Commodity Futures Trading Comm'n v. Savage*, 611 F.2d 270, 282 (9th Cir.1979). In a motion for summary judgment, the court must view the facts in the light most favorable to the non-moving party. *State Farm Fire and Cas. Co. v. Martin*, 872 F.2d 319, 320 (9th Cir.1989).

Defendants contend that the plain language of their medical plan grants them the clear discretion and authority to determine whether a procedure is

experimental or investigational.[8] In contrast, Plaintiffs claim that this Plan language is ambiguous. In support, Plaintiffs rely on excerpts of other portions of the Plan that do not deal specifically with experimental or investigational treatments.

The Court has reviewed those excerpts cited by Plaintiffs in the context of their surrounding language and find that they give no indication of saving coverage for experimental or investigational treatment. Moreover, Plaintiffs fail to specifically point to or conclusively explain how the determination of whether a treatment is experimental or investigational is not within the discretion of the Plan administrator. Lastly, the Plan language at issue states that "[A]ll decisions and interpretations of the Committee made in good faith pursuant to the Plan shall be final, conclusive and binding on all persons, subject only to the claims procedure, and may not be overturned unless found by a court to be arbitrary and capricious." *Id.*

Thus, this Court's review is limited to whether or not Defendants abused

[8]This is found in the relevant language in the "experimental and investigational" provision stating that ". . . medical procedures . . . at the time provided or sought to be provided, are in the judgment of BCBS not recognized as conforming to generally accepted medical practice . . ." *SISTERS OF CHARITY MEDICAL PLAN, AFFIDAVIT OF GENE LAMPE, EXHIBIT A.* In addition, Article IV, 4.1(b) of Defendant Sisters of Charity System's Health Benefits Plan states that "the Committee shall have complete discretion to interpret the provisions of the Plan . . ." *Id.*

their discretion when they denied Plaintiffs' request for coverage. Where the plan "unambiguously provide[s] discretion to [its] administrator" to interpret the terms of the plan and make final benefits determinations, the determination is reviewed for an abuse of discretion. *Abatie v. Alta Health & Life Ins. Co.,* 458 F.3d 955, 963 (9th Cir.2006).[9] "The plan administrator bears the burden of showing the plan gives it discretionary authority." *Ondersma v. Metro. Life Ins. Co.,* 2006 WL 3334941, at *1, 2006 U.S. Dist. LEXIS 85460, at *2 (N.D.Cal. Nov. 16, 2006).

As reflected above, the Defendants' Plan states, in various provisions, that Defendants retain discretion to interpret the provisions of the Plan. After a thorough review of the Medical Plan, this Court concludes Defendants have sufficiently met their burden of showing that it unambiguously gives them discretionary authority to interpret the terms of the Plan and make final benefits determinations. Thus, this Court shall review the denial of coverage for abuse of discretion.

IV. DISCUSSION

The crux of this case is whether Defendants abused their discretion in denying Parsons coverage for her participation in a stem-cell transplant (ABMT)

[9]Although *Abatie* deals with an ERISA plan where our present plan does not, this Court finds no reason why the same analysis regarding discretionary authority should not apply.

clinical trial for the treatment of her refractory Crohn's disease. All of Plaintiffs' claims rise or fall based on this Court's ruling on this issue.

A. The Consent Form

Defendants denied benefits for Parsons's participation in Dr. Burt's clinical trial on the grounds that it was (1) experimental and investigational and (2) not medically necessary. As noted *supra*, in order to be "medically necessary," a treatment must not be experimental and investigational. Defendants allege that the relevant Plan language at issue denies coverage if a medical procedure "[I]s one in which the improvement claimed is not demonstrated to be obtainable outside the Experimental and Investigational setting."[10] Defendants then refer to the consent form for Dr. Burt's clinical trial that Parsons was required to sign. That consent form contains the following relevant language:

- You are being asked to take part in a research study.
- You are being asked to participate in an experimental research study because you have severe Crohn's Disease that is progressive and accelerated.
- We stress that this is an experimental procedure.
- It is important to know that this experimental procedure is risky, may not work, and may have serious complications including death.

[10]*SISTERS OF CHARITY MEDICAL PLAN, AFFIDAVIT OF GENE LAMPE, EXHIBIT A*

- Although the Isolex 300i System has been FDA approved for use in some transplants for cancer, it is still experimental for use with your type of disease.

- There may be no direct benefit to you by your participation in this research study. However, it is hoped that this treatment will slow, decrease, stop, or reverse progression of your severe Crohn's Disease. However, this research study is risky, of no proven benefit, and may not work.

- The results of this study may also be used for teaching, publications, or presentations at scientific meetings.

- You do not have to take part in this research study.[11]

There is no dispute that Parsons voluntarily signed this consent form. The consent form is replete with the words "experimental", "research" and "study" and makes clear that the clinical trial is "risky, of no proven benefit, and may not work." In addition, a reading of Dr. Burt's deposition and his discussion of the consent form does not contradict the presence or commonly-recognized meanings of these terms.

Moreover, the language in the consent form implicitly recognizes that ABMT treatment is not standard therapy for Crohn's disease: "[Y]ou do not have to take part in this research study. If you do not wish to participate in this study, ***standard therapy*** includes steroids, azathioprine, metronidazole or sulfasalazine.

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[11]*REPLY BRIEF OF DEFENDANT SISTERS OF CHARITY HEALTH SYSTEM, INC. ON MOTION FOR SUMMARY JUDGMENT (Doc. # 30), Exhibit 1.*

You can consider alternate therapies for your disease and can seek the opinion of other physicians."[12] The very language of the consent form leads to the conclusion that ABMT is not a standard therapy alternative for Crohn's disease.

Finally, Plaintiffs do not dispute the presence of these words and phrases in the consent form. In fact, none of Plaintiffs' response briefs or supplemental brief in opposition to either of Defendants' motions for summary judgment even discuss the problematic nature this consent form has to Plaintiffs' claims. From the consent form alone this Court concludes that Defendants did not abuse their discretion in denying coverage on the grounds that the clinical trial was experimental and investigational and not medically necessary.

B. PEER-REVIEWED LITERATURE

In appealing the denial of benefits to the Benefits Administration Committee, Plaintiffs submitted, among other things, Dr. Burt's peer-reviewed literature regarding ABMT treatment for Crohn's disease. It is undisputed that the Committee reviewed these submissions and that they sought external independent review of these submissions from gastroenterologists.

Defendants further note that the peer-review articles that were provided by Dr. Burt and presented to the Benefits review committee did not conclusively

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[12] *Id.*

establish that the ABMT procedure as applied to Crohn's disease was not experimental and investigational in nature. In fact, a peer-review article co-authored by Dr. Burt clearly states that the effectiveness of ABMT treatment for Crohn's disease as a viable treatment plan still needed to be confirmed by randomized trials.[13] In Dr. Burt's deposition, he acknowledges that no randomized tests applying ABMT procedures to Crohn's disease have been conducted. According to Dr. Burt, this is because Crohn's disease patients are unwilling to chance being the "control" in randomized testing when his ABMT treatment was so effective.[14] But the fact remains that randomized testing still needs to be performed in order to confirm efficacy. Accordingly, Defendants' reliance on this ground in denying coverage is not an abuse of discretion.

C. INDEPENDENT REVIEW

Plaintiffs acknowledge Defendants sought three different outside independent reviews regarding their request for coverage of the clinical trial. One of the reviewers, independent review group National Medical Reviews, Inc., was asked by Defendants to review its denial of Parsons request to participate in Dr. Burt's clinical trial. The reviewer was a gastroenterologist and he reviewed

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[13] *AFFIDAVIT OF GENE LAMPE (Doc.# 24), ¶ g.*

[14] *DEPOSITION OF DR. BURT, pp. 167-168.*

Parsons's medical history as well as articles relating ABMT applications to Crohn's disease. The independent reviewer upheld the Defendants' denial and concluded that "based on the clinical documentation submitted . . . the participation in the clinical trial and the use of bone marrow transplant is considered experimental and the previous denial should be upheld."[15]

Plaintiffs argue Defendants should not have used gastroentrologists to review the denial of coverage for the clinical trial because a gastroenterologist is not qualified to review ABMT treatment's for Crohn's disease. Rather, per the Plaintiffs' request, Defendants should have engaged a hematologist or transplantist familiar with bone marrow transplants to review Dr. Burt's request for coverage for Parsons's admission into his clinical trial. As such, Plaintiffs allege Defendants abused their discretion.

The record reflects that the reviewing physicians that upheld the denial of coverage specialized in gastroenterology. It is undisputed that Crohn's disease is a disease of the intestine and as such, falls under the purview of gastroenterology. Plaintiffs' claim that the ABMT treatment for Crohn's disease is not experimental or investigational, yet in the same breath, they also contend that a gastroenterologist is not qualified to review Defendants' denial of coverage. If

[15] *AFFIDAVIT OF GENE LAMPE (Doc.# 24), Attachment 23d.*

ABMT treatment was a recognized therapy for Crohn's disease, as Plaintiffs would have this Court believe, surely a gastroenterologist familiar with the treatment of intestinal diseases like Crohn's disease would be qualified to review Defendant's denial of coverage. The fact that Plaintiffs argue Defendants' gastroenterologist reviewers are not qualified to review their request for coverage reflects how far afield the use of ABMT treatment is from generally accepted Crohn's disease treatment. Plaintiffs cannot have it both ways. If, as Plaintiffs would like this Court to hold, ABMT is a recognized and non-experimental therapy for Crohn's disease, then the independent gastroenterologist reviewers should be qualified to review Plaintiffs' claims for coverage. For those reasons, the Court cannot conclude that Defendants abused their discretion in having gastroenterologists independently review the request for coverage.

D. FINAL APPROVAL TO MARKET

Plaintiffs argue that the ABMT clinical trial had received FDA and NIH approval and therefore was not experimental or investigational. However, it is undisputed that there are varying levels of FDA approval. Here, there is evidence that the ABMT trial had received Phase II approval from the FDA. But the ABMT trial has not received "final approval to market" as stated in the Plan's definition of experimental and investigational. Thus, Defendants did not abuse their discretion

when they denied coverage on this ground.

E. PLAINTIFFS' CASES

Plaintiffs cite numerous cases in support of their argument that Defendants abused their discretion in denying coverage for ABMT therapy on the grounds that the treatment was still investigational and experimental. *E.g. Boldon v. Humana Insurance Company,* 466 F.Supp.2d 1190 (D.Az. 2006)*; Lafferty v. Providence Health Plans,* 706 F.Supp.2d 1104 (D.Or. 2010)*; Am. Investors Life Ins. Co. v. Butler,* 76 Ark. 355 (Ark. Ct. App. 2002). Based on these cases, Plaintiffs argue that because Dr. Burt's clinical trial had some FDA approval and was covered by Medicare/Medicaid, it was not investigational and experimental. Plaintiffs also argue that the Plan's terms were ambiguous.

In *Boldon*, the Court found that because defendant Humana had an inflexible existing guideline that precluded any coverage for TheraSphere treatment on the grounds that it was experimental/investigational, there was no discretionary review of plaintiff's request for coverage. 466 F.Supp.2d 1190(Dist. Az. 2006). As such, the outcome was decided before any medical history of plaintiff had even been reviewed. Based on this lack of review, the *Boldon* court concluded that Humana had abused its discretionary authority. Additionally, the record in *Boldon* established that TheraSphere treatment had become recognized as standard therapy

for cancer treatment in at least thirty cancer treatment centers in the United States.

Boldon is easily distinguishable. First, Defendants have no inflexible pre-existing guideline precluding ABMT procedures as experimental or investigational. Second, the record reflects that outside of Northwestern University, where Dr. Burt's ABMT trial was run, there are but a handful of "investigational centers of excellence under overview of institutional research boards" where ABMT treatment for Crohn's disease is being performed.[16]

Next, Plaintiffs rely on *Lafferty*, which held that the fact that a treatment is still under continued testing and research does not conclusively establish it is experimental and investigational. 706 F.Supp.2d 1104. Plaintiffs further argue that, like *Lafferty*, there is no gold standard for the treatment of the type of Crohn's disease that Parsons suffers from.

First, due to "significant procedural irregularities" by the Defendant in *Lafferty*, the applicable standard of review in that case was heightened from abuse of discretion to *de novo* review. *Id.* As there is no evidence of procedural irregularities in this case, this case is distinguishable from *Lafferty.*

Second, unlike the present case, the *Lafferty* court had evidence that the plaintiff's requested treatment was used in the local community and there were at

[16] *AFFIDAVIT OF GENE LAMPE (Doc.# 24), ¶ 19.*

least six specialized centers across the United States that performed the procedure. Finally, the *Lafferty* court noted there were many scientific articles contradicting the defendant's argument that the procedure at issue was experimental and investigational. *Id.* These facts are not present here. Further, unlike *Lafferty*, the clinical trial at issue specifically states that it is a research study and is experimental in nature.

Next, Plaintiffs cite *Am. Investors Life Ins. Co. v. Butler,* 76 Ark. App. 355 (Ark.Ct.App. 2002) for its holding that an "experimental" provision in a policy that excluded coverage did not apply. In *Butler,* the policy at issue had a broad exclusion for experimental treatment, yet it had another provision that dealt specifically with coverage for stem-cell procedures. Accordingly, the *Butler* Court concluded that if certain conditions are met, that procedure, even if experimental, would be a covered expense, and therefore the policy was ambiguous.

Here, there is a broad exclusion against experimental and investigational procedures and there is no specific provision for the coverage of stem-cell or ABMT treatments. As such, *Butler* is also inapplicable.

In addition, Plaintiffs also cite *Butler* in arguing that the Plan's consultation provision is ambiguous. That provision states "BCBS may contract with health care consultants to work with you and your Doctor in identifying the most

appropriate and effective program using alternative, accelerated or palliative care. If you, your Doctor, and the consultants are able to agree on a treatment program, the consultants' program shall expand the Plan to include services, supplies and treatment otherwise not covered under the Plan or expand Benefits which are covered, but may have internal limitations."[17] In determining whether an insurance contract is ambiguous, the terms must be given their usual meaning and construed using common sense. *Newbury v. State Farm & Cas. Ins. Co. of Bloomingon, Ill.,* 343 Mont. 279, 284 (Mont. 2008). In the Court's view, the Plan's consultation provision is plain and unambiguous and does not conflict with the Plan's express exclusion of "Services and supplies that are not medically necessary . . . Services, supplies or drugs that are Experimental or Investigational."[18]

Moreover, a consultation did occur between BCBS' Dr. Koren and Dr. Burt. After two conversations, however, Dr. Koren avers that he received no additional information that would lead him to conclude that ABMT treatment for Crohn's disease was anything but investigational and experimental.[19] As such, there was no agreement as to an ABMT treatment plan.

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[17] *AFFIDAVIT OF GENE LAMPE (Doc.# 24), Exhibit A.*

[18] *Id.*

[19] *AFFIDAVIT OF DR. JAMES KOREN, M.D., Doc. # 29.*

V. CONCLUSION AND ORDER

Although the Court is very sympathetic to Parsons's situation, Defendants' Plan clearly excludes coverage for services and supplies that are experimental and investigational. The record reveals several reasons to conclude Defendants did not abuse their discretion in denying Plaintiffs' request for coverage for Dr. Burt's clinical trial.

The peer-reviewed literature co-authored by Dr. Burt himself states that randomized trials still needed to be performed in order to test the efficacy of ABMT treatment for Crohn's disease. Three independent reviewers who were familiar with Crohn's disease also affirmed the Defendants' denial. Most importantly, the consent form that Parsons signed in order to participate in Dr. Burt's ABMT clinical trial specifically stated that the procedure was experimental, for research, and was "risky, of no proven benefit, and may not work."

For those reasons, IT IS HEREBY ORDERED as follows:

1. Defendant Sisters of Charity's Motion for Summary Judgment (*doc. 21*) is GRANTED; and

2. Defendant BCBS' Motion for Summary Judgment (*doc. 27*) is GRANTED;

The Clerk of Court is directed to enter judgment in favor of Defendants, notify the parties of the entry of this Order, and close this case.

DATED this 31st day of May, 2011.

/s/ Richard F. Cebull
RICHARD F. CEBULL
U. S. DISTRICT JUDGE